



# American Bakers Association

*Serving the Baking Industry Since 1897*

August 30, 2002

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, Maryland 20852

Re: Docket No. 02N-0277; Solicitation for Comments, Section 306,  
Establishment and Maintenance of Records  
PL107-188 (July 17, 2002)

Dear Sir/Madam:

These comments are submitted on behalf of the members of the American Bakers Association (ABA), the national trade association representing the wholesale baking industry. ABA membership consists of bakers and bakery suppliers who together are responsible for the manufacture of approximately 80 percent of the baked goods sold in the United States. The purpose of these comments is to provide information to FDA regarding establishment and maintenance of records for food facilities, specifically bakery facilities, under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (PL 107-188) as the agency proceeds to develop a proposed rule on this issue.

ABA welcomes the opportunity to provide information and assist the agency in developing an appropriate approach for establishing and maintaining records for bakery facilities with regards to food security. As ABA understands it, the primary purpose of the soon to be proposed recordkeeping regulations is to assist the Secretary of Health and Human Services in establishing a system to identify records for the immediate previous sources and immediate subsequent recipients for a specific food including its packaging (one step back and one step forward). Such records should allow FDA to address credible threats of serious adverse health consequences or death to humans or animals. This recordkeeping regulation would apply to entities that manufacture, process, pack, transport, distribute, receive, hold or import food (excluding farms and restaurants).

02N-0277

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What Information is Appropriate for Recordkeeping?

The records required of each company should determine, to the extent possible, the immediate previous sources and subsequent immediate sources of the food and its packaging (one step back and one step forward). The ability of a company to identify the exact immediate source of specific food will vary considerably and is not necessary for FDA to accomplish its charge. The degree of specificity with which immediate previous sources can be identified will vary based on numerous factors including the commingling of foods - that is how foods and ingredients are handled, used in the production process, stored and distributed. FDA should recognize that in some cases, information can be obtained that will allow a reduction in the number of potential sources for a specific food, but not necessarily identify the exact immediate previous source. Additionally identification of a specific contact person should not be required.

What Records Should be Established and Maintained?

Existing business records such as invoices and purchase orders that accurately disclose a company's suppliers, co-packers, independent distributors and customers of ingredients or finished goods should be appropriate records with the need for modifications to be determined and acted on by the relevant company.

ABA strongly believes that FDA should not require new and unnecessary records. Given that Section 414(b) of the Federal Food Drug and Cosmetic Act (FFDCA) potentially affects a huge number of businesses, ABA believes it would be impractical and unnecessary to impose a single, specified record system that does not provide the needed flexibility to accommodate diversity of the channels of trade for food. It would be useful for FDA to determine how the term "transaction" will be applied beyond routine and customary business transactions, as it could aid in establishing how existing business records can satisfy the new statutory requirement in PL107-188.

Lastly, ABA believes that FDA should consider providing flexibility for existing recordkeeping systems and insure that corporate proprietary information is not compromised.

Who is required to establish and maintain records?

ABA believes that companies should be responsible and accurate in their recordkeeping and that FDA should also create a transparent system in working with companies when questions of food security occur. Dealing with such matters in a

American Bakers Association  
Docket No. 02N-0277  
August 30, 2002  
Page 3

timely manner can be critical. FDA should be willing to waive its traditional Freedom of Information Act (FOIA) requirements when working with companies to quickly answer questions regarding food security issues. Working together and assuring that records of the agency and company are analogous on food security recordkeeping and registration issues will be imperative in effectively handling such issues.

ABA members are dedicated to insuring a sanitary environment for production of its products and for providing a wholesome food supply for its customers. The baking industry is very sensitive to and already adheres to the current high food packaging standards and good manufacturing practices for packaging of its products. Information regarding packaging should be restricted to the food contact portion of the package and not extend beyond the packaging manufacturer with respect to information about immediate previous source – that is the sources of materials used by the packaging manufacturer are not appropriate as immediate previous source(s).

How should the size of a business be considered in promulgating regulations?

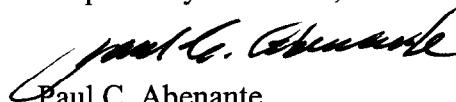
The size of a business should be considered in establishing appropriate implementation/effective dates for the proposed regulation. Consideration should be given to exempting selected business based on size. Additionally, a phase-in period of six months should be provided to allow all businesses to make any needed adjustments to their current practices before implementation of new regulations.

How long should records be maintained?

ABA supports the statutory requirement included in PL 107-188 limits recordkeeping to two years.

ABA appreciates this opportunity to comment on FDA's request for information regarding establishment and maintenance of records as it applies to Public Law 107-188. This issue is of great interest to the wholesale baking industry. The technical contact for these comments is Lee Sanders, ABA Vice President, Regulatory and Technical Services, American Bakers Association, 1350 I Street, N.W., Suite 1290 Washington, D.C. 20005-3305 (telephone) 202-789-0300, (fax) 202-898-1164.

Respectfully submitted,



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